ASAM American Society *of* Addiction Medicine

March 26, 2025

The Honorable Pam Bondi
Attorney General of the United States
Department of Justice
950 Pennsylvania Avenue NW
Washington DC 20530

The Honorable Derek S. Maltz
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Re: Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative

Dear Attorney General Bondi and Acting Administrator Maltz:

On behalf of the **American Society of Addiction Medicine (ASAM), R Street Institute (RSI), National Community Pharmacists Association (NCPA), American Society of Health-System Pharmacists (ASHP), and National Commission on Correctional Health Care (NCCHC)**, the undersigned congratulate Ms. Bondi on becoming the 87th Attorney General of the United States, and Mr. Maltz on being appointed Acting Administrator of the Drug Enforcement Administration (DEA). ASAM is a national medical specialty society representing more than 8,000 physicians and associated health professionals who specialize in the prevention and treatment of addiction. RSI is a leading think tank focused on solving complex public policy challenges through free markets and limited, effective government; it offers pragmatic, real solutions that foster American innovation, bolster competition, and safeguard individual liberty. NCPA is the voice for the community pharmacist, representing over 18,900 pharmacies that employ more than 205,000 individuals nationwide. ASHP is the largest association of pharmacy

professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. NCCHC is a nonprofit organization with a mission to improve the quality of health care in jails, prisons, and juvenile confinement facilities; it is supported by the major national organizations representing the fields of health, mental health, law, and corrections. ASAM, RSI, NCPA, ASHP, and NCCHC look forward to working with the U.S. Department of Justice (DOJ)/DEA team on addressing the nation's deadly addiction and overdose crisis.

To that end, and consistent with the February 19, 2025 Executive Order, titled "Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative," we respectfully request that DOJ/DEA identify 21 C.F.R. § 1306.07(a) - to the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget - as a regulation that is not based on the best reading of the underlying statute (21 U.S.C. 823(h)) and constitutes a significant regulatory action that materially harms competition in health care delivery.[i,ii,iii]

The current regulation's ban on prescribing methadone for the treatment of opioid use disorder (OUD) not only misinterprets the plain language of the underlying statute but also creates an unnecessarily burdensome bureaucracy that harms Americans by restricting patient choices and limiting the autonomy of qualified practitioners[ii] **in addiction medicine. Consequently, the current regulation prevents qualified practitioners from fighting the drug cartels - on the demand side - alongside you.**

In medicine, a one-size-fits-all approach often does not work. In addiction medicine, all pathways to recovery must be available. Specifically, treatment of OUD with methadone is associated with a 50% lower risk of death from any cause among people with OUD, as well as reductions in crime and illicit drug use, and increased retention in addiction treatment which can facilitate employment and productivity.[iv] However, methadone treatment for OUD is only used by about 500,000 people in the U.S. each year,[v] a small fraction of the approximately 5.7 million Americans with OUD.[vi] While buprenorphine and extended-release naltrexone are also effective medications for OUD, they are not the right choice for everyone. **Some Americans with OUD – particularly those using high-potency synthetic opioids like fentanyl – may require methadone to stabilize and achieve recovery.** In a recent study, patients with OUD in British Columbia who were treated with buprenorphine/naloxone were 60% more likely to discontinue treatment than those who received methadone.[vii]

The most efficient way for more Americans to access methadone in integrated care models - including primary care and behavioral health services - is through qualified practitioners prescribing it and pharmacies dispensing it. Yet, for more than fifty years, the overly burdensome regulation in 21 C.F.R. § 1306.07(a) has prohibited qualified practitioners from prescribing methadone for OUD and pharmacies from filling such prescriptions. As a result, patients who need methadone for OUD have been severely limited in their choice of providers, restricted to a single type of treatment program – a "methadone" clinic/opioid treatment program (OTP), rigidly defined by federal regulations. Approximately 80% of US counties do not have a single OTP,[viii] while there are more than 61,000 community pharmacies nationwide.[ix] Simultaneously, private equity firms have an outsized presence in the national OTP infrastructure compared to other health care sectors, which may have negative implications for market dynamics, such as pricing, and patient care.[iii] **The status quo cannot continue.**

A 2022 report by the GW Regulatory Studies Center[x] notes that nowhere in the underlying statute (21 U.S.C. 823(h)) is there an explicit prohibition on practitioners prescribing methadone for OUD or pharmacies from dispensing it under a prescription. Instead, the statutory language requires practitioners who "dispense" narcotic drugs for maintenance or detoxification to annually obtain a separate registration for that purpose. Federal statute defines "dispense" (21 U.S.C. 802 (10)) as "deliver[ing] a controlled substance to an ultimate user . . . by . . . a practitioner, including the prescribing and administering of a controlled substance." As noted in the same 2022 report, a key question is how to interpret "including the prescribing and administering" language in the definition of "dispense."

In the context of 21 U.S.C. 823(h), the language could mean either:

1. Prescribing <u>or</u> administering constitutes dispensing, allowing DEA to issue separate registrations to qualified applicants for (a) prescribing methadone for OUD or (b) administering or dispensing it *pursuant to a prescription issued by an authorized practitioner* (in addition to separate registrations for qualified applicants that order and dispense *directly*, currently limited to OTPs by federal regulations); or
2. Only the act of prescribing <u>and</u> administering together constitutes dispensing necessitating a separate registration – that is, the separate registration requirement only applies to applicants seeking to order for administration/dispensing *directly* Schedule II narcotic drugs to individuals for maintenance treatment or detoxification treatment, but <u>not</u> to applicants seeking to prescribe, or applicants seeking to administer or dispense *pursuant to a prescription*. The meaning under this second interpretation arises, because it would

be unusual to interpret "dispense" broadly (i.e., including "prescribe") in the first sentence of 21 U.S.C. 823(h) but narrowly (i.e., excluding "prescribe") in the second.

Notably, under any interpretation, the DEA's prescribing prohibition in 21 C.F.R. § 1306.07(a) is not mandated by the plain meaning of the underlying statutory text. While Congress could have explicitly excluded "prescribe" from "dispense" in the second sentence of 21 U.S.C. 823(h) - like DEA has unilaterally done in regulation - Congress did not. Moreover, when it comes to pharmaceutical controlled substances, DEA's responsibility is to prevent diversion and misuse,[xi] not to regulate the practice of medicine. Under either interpretation, DEA retains authorities needed to fulfill its mission, including through the setting of standards for securing stock of, and maintenance of records on, Schedule II medications, including methadone for OUD – whether through a separate registration specifically for stocking methadone for OUD for purposes of administering/dispensing it pursuant to a prescription issued by an authorized practitioner, or a pharmacy registration.[xi] Finally, it is hard to justify the public policy outcome that would result from continuing to interpret federal law as if Congress intended to permanently ban in-person prescribing of methadone, even by addiction specialist physicians (a medical subspeciality that did not exist in 1974),[xii,xiii] for the *treatment* of OUD – now that (1) the U.S. Department of Health and Human Services (HHS) has relaxed rules on take-home supplies dispensed from OTPs, which can be ordered by non-physician OTP practitioners[xiv] and (2) Congress has authorized and directed DOJ/DEA to issue special registrations for the telemedicine prescribing of controlled substances.[xv]

For these reasons, we urge the Trump Administration to develop a Unified Regulatory Agenda that seeks to modify the overly burdensome regulation at 21 C.F.R. § 1306.07(a), which currently bans qualified prescribers from prescribing methadone for OUD and pharmacies from administering/dispensing it pursuant to a prescription. Additionally, DOJ/DEA should clarify whether it intends to:

1. Work with the HHS Secretary on regulations to issue separate registrations under 21 U.S.C. 823(h), permitting qualified prescribers to prescribe methadone for OUD and qualified pharmacies to administer or dispense it under such prescriptions; or
2. Interpret 21 U.S.C. 823(h) as inapplicable to practitioners (including pharmacies) that do not *directly* dispense methadone for OUD but have DEA registrations that include Schedule II authorities for prescribing, or for administering/dispensing Schedule II prescriptions issued by an authorized practitioner.

Thank you for considering this urgent request. Continuing to separate OUD treatment with methadone from other medical care has not only created significant access barriers

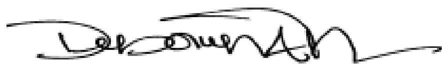
to this lifesaving medication for Americans with OUD, but it is not supported by the plain meaning of the underlying statute. By working together, we can finally usher in more patient-centered health care reforms in addiction medicine that allow qualified prescribers to deliver the medical care that best addresses their patients' needs.[ii] **In short, please equip qualified practitioners with the tools they need to fight the drug cartels, too.**

We look forward to your response and are available to meet at your convenience. If you have any questions about this letter or wish to discuss this matter further, then please contact Kelly Corredor, ASAM's Chief Advocacy Officer, at kcorredor@ASAM.org.

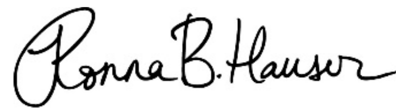
Sincerely,

Brian Hurley, MD, MBA, FAPA, DFASAM
President
American Society of Addiction Medicine

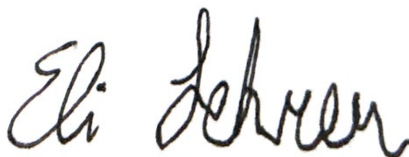
Tom Kraus, JD
Vice President, Government Relations
American Society of Health-System Pharmacists



Deborah A. Ross, CCHP
Chief Executive Officer
National Commission on Correctional Health Care



Ronna B. Hauser, PharmD
Senior Vice President, Policy & Pharmacy Affairs
National Community Pharmacists Association



Eli Lehrer
President, R Street Institute

cc: The Honorable Robert F. Kennedy Jr., Secretary, U.S. Department of Health and Human Services

---

[i] Senators Markey, Braun Push Opioid Treatment Programs for Answers on Private Equity Investments | U.S. Senator Ed Markey of Massachusetts. Senate.gov. Published December 12, 2024. Accessed March 13, 2025. https://www.markey.senate.gov/news/press-releases/senators-markey-braun-push-opioid-treatment-programs-for-answers-on-private-equity-investments

[ii] The Heritage Foundation. *Mandate for Leadership: The Conservative Promise*.; 2023. https://static.project2025.org/2025_MandateForLeadership_FULL.pdf (stating on page 450: "Goal #2: Empowering Patient Choices and Provider Autonomy. Basic economics holds that costs tend to decrease and quality and options tend to increase when there is robust and free competition in the provision of goods and services. Health care is no exception. Health care reform should be patient-centered and market-based and should empower individuals to control their health care–related dollars and decisions. Of course, providers who deliver health care also need the freedom to address the unique needs of their patients.")

[iii] Zhu DT, Song Z, Kannan S, Cai CL, Bajaj SS, Gondi S. Private Equity Ownership of US Opioid Treatment Programs. *JAMA Psychiatry.* 2025;82(2):204–206. doi:10.1001/jamapsychiatry.2024.4011

[iv] Dydyk AM, Jain NK, Gupta M. Opioid Use Disorder. [Updated 2024 Jan 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK553166/

[v] *TECHNICAL BRIEF: CENSUS of OPIOID TREATMENT PROGRAMS*.; 2022. Accessed March 15, 2025. https://nasadad.org/wp-content/uploads/2022/12/OTP-Patient-Census-Technical-Brief-Final-for-Release.pdf

[vi] Substance Abuse and Mental Health Services Administration. (2024). Key substance use and mental health indicators in the United States: Results from the 2023 National Survey on Drug Use and Health (HHS Publication No. PEP24-07-021, NSDUH Series H-59). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/report/2023-nsduh-annual-national-report

[vii] NIDA. 2024, July 29. To address the fentanyl crisis, greater access to methadone is needed. Retrieved from https://nida.nih.gov/about-nida/noras-blog/2024/07/to-address-the-fentanyl-crisis-greater-access-to-methadone-is-needed on 2025, March 18; Nosyk B, Min JE, Homayra F, et al. Buprenorphine/Naloxone vs Methadone for the Treatment of Opioid Use Disorder. *JAMA*. 2024;332(21):1822–1831. doi:10.1001/jama.2024.16954

[viii] J.H. Duff and J.A. Carter, "Location of Medication-Assisted Treatment for Opioid Addiction: In Brief" (Congressional Research Service, 2019), https://www.everycrsreport.com/files/20190624_R45782_ed39091fadf888655ebd69729c3180c3f7e550f6.pdf.

[ix] Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. J Am Pharm Assoc (2003). 2022 Nov-Dec;62(6):1816-1822.e2. doi: 10.1016/j.japh.2022.07.003. Epub 2022 Jul 15. PMID: 35965233.

[x] Dooling B, Stanley L. *A Vast and Discretionary Regime Federal Regulation of Methadone as a Treatment for Opioid Use Disorder*.; 2022. Accessed March 10, 2025. https://regulatorystudies.columbian.gwu.edu/sites/g/files/zaxdzs4751/files/2022-08/gw-reg-studies_report_federal-methadone-regulations_bdooling-and-lstanley.pdf

[xi] Diversion Control Division | Publications & Manuals. www.deadiversion.usdoj.gov. https://www.deadiversion.usdoj.gov/pubs/manuals/manuals.html

[xii] American Society of Addiction Medicine. Recognition and Role of Addiction Specialist Physicians in Health Care in the United States. Default. Published January 28, 2022. Accessed March 15, 2025. https://www.asam.org/advocacy/public-policy-statements/details/public-policy-

statements/2022/01/28/public-policy-statement-on-the-recognition-and-role-of-addiction-specialist-physicians-in-health-care-in-the-united-states

[xiii] Nunes EV, Kunz K, Galanter M, O'Connor PG. Addiction Psychiatry and Addiction Medicine: The Evolution of Addiction Physician Specialists. Am J Addict. 2020 Sep;29(5):390-400. doi: 10.1111/ajad.13068. PMID: 32902056.

[xiv] The 42 CFR Part 8 Final Rule Table of Changes. Samhsa.gov. Published 2024. Accessed March 13, 2025. https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

[xv] 21 U.S.C. 831(h)